



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Option License: The Development of a Single Domain Human Anti-Mesothelin Monoclonal Antibody as a Bispecific Antibody for the Treatment of Human Cancers.

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive start-up option license to practice the inventions embodied in U.S. Patent Application 61/706,396 entitled “Mesothelin Antibodies And Methods For Eliciting Potent Antitumor Activity” [HHS Ref. E-236-2012/0-US-01], PCT Application PCT/US2013/059883 entitled “Mesothelin Antibodies And Methods For Eliciting Potent Antitumor Activity” [HHS Ref. E-236-2012/0-PCT-02], and all related continuing and foreign patents/patent applications for the technology family, to Oncolinx Pharmaceuticals, LLC. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive start-up option licensed territory may be worldwide, and the field of use may be limited to:

The use of bispecific antibodies having:

- (a) the complementary determining regions (CDRs) of the monoclonal antibody SD1; and
- (b) the CDRs of an anti-CD3 antibody,

for the treatment of mesothelin-expressing cancers. The Licensed Field of Use explicitly excludes the use of the CDR sequences of SD1 in a monospecific antibody, or in the form of an immunotoxin, antibody-drug conjugate, or chimeric antigen receptor.

Upon the expiration or termination of the exclusive start-up option license, Oncolinx Pharmaceuticals, LLC will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive start-up option license with no greater field of use and territory than granted in the exclusive start-up option license.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4632; Facsimile: (301) 402-0220; E-mail: lambertsond@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This invention concerns a monoclonal antibody and methods of using the antibody for the treatment of mesothelin-expressing cancers, including mesothelioma, lung cancer, ovarian cancer and pancreatic cancer. The specific antibody covered by this technology is designated SD1, which is a single domain, fully human monoclonal antibody against mesothelin.

Mesothelin is a cell surface antigen that is preferentially expressed on certain types of cancer cells. The SD1 antibody can selectively bind to these cancer cells and induce cell death

while leaving healthy, essential cells unharmed. This can result in an effective therapeutic strategy with fewer side effects due to less non-specific killing of cells.

The prospective exclusive start-up option license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive start-up option license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive start-up option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 27, 2015.

Richard U. Rodriguez,
Acting Director,
Office of Technology Transfer,
National Institutes of Health.

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